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MCKEE, VOORHEES & SEASE, P.L.C.
ATTN: PIONEER HI-BRED
801 GRAND AVENUE, SUITE 3200
DES MOINES, IA 50309-2721

EXAMINER

MEHTA, ASHWIN D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1638

DATE MAILED: 06/02/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,708

Applicant(s)

HENKE, GARY E.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,20 and 42-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7,51,52 and 54 is/are allowed.
- 6) ☒ Claim(s) 8,42-49,53 and 55-63 is/are rejected.
- 7) ☒ Claim(s) 20 and 50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to the specification for the presence of blank lines is withdrawn, in light of the assurances that seed of Pioneer inbred lines GE565937 and GE502199 will be deposited, and the ATCC accession number inserted into the specification, at the time of allowance.
3. The objection to claims 12, 16, 25, and 29 is withdrawn, in light of the cancellation.
4. The rejections of claims 1-7 and 9-41 under 35 U.S.C. 112, 2nd paragraph, are withdrawn, in light of the claim amendments or cancellations.
5. The rejection of claim 33 under 35 U.S.C. 112, 1st paragraph is withdrawn, in light of its cancellation. Applicant has also provided written assurance that inbred maize plants GE565937 and GE502199 will be deposited with the ATCC upon receipt of notice of allowable claims, and that the deposit will meet the requirements of 37 CFR 1.801-1.809 (response received 26 March 2003, page 9, 2nd paragraph and the paragraph bridging pages 13-14).

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Claim Objections

6. Claims 20 and 50 are objected to under 37 CFR 1.75 (b) as being duplicate claims. Both claims are drawn to a maize plant, or its parts, having all the morphological and physiological characteristics of hybrid maize plant X1139Y. Both claims have the same scope. Applicant is required to cancel one of the claims, or amend the claim(s).

Claim Rejections - 35 USC § 112

7. Claim 8 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 26 December 2002 under item 6. Applicant traverses the rejection in the paper received 26 March 2003. Applicant's arguments were fully considered but were not found persuasive.

Applicant argues that support can be found on pages 2 and 13, that there are several modes of conferring male sterility, and that one skilled in the art would not find the terminology indefinite (response, page 11, last paragraph). However, the recitation "or other factors" in the passage on page 13 pointed out by Applicant, does not clearly define what the other factors are. Further, it is also not clear if the plant of claim 8 is transgenic, as the plant of claim 2 may have been transformed with a transgene that confers male sterility.

8. Claims 43-49, 55, 57, 61, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claims 43 and 47: the recitation "value added trait gene" in line 3 of the claims renders them indefinite. The specification does not clearly define the recitation. Page 44 provides examples of value added trait genes. However, the recitation "such as" in line 18 of page 44 does not provide a clear indication of what other genes are value added trait genes.

Further in claims 43 and 47: the claims are indefinite because there is improper antecedent basis for "The maize plant of claim 42 (or 46)" in line 1. Claims 42 and 46 are directed to methods, not a maize plants.

In claims 44 and 48: the recitation "derivative thereof or a synthetic polypeptide modeled thereto" renders the claims indefinite. It is not clear what is considered to be a "derivative", or what is encompassed by a polypeptide that is "modeled". The metes and bounds of the claims are unclear.

In claim 44: the claim is indefinite because the last line of the claim is not consistent with the preamble. The first line of the claim indicates that the claim is directed to a method of developing a backcross conversion X1139Y hybrid maize plant. However, the last line indicates that a transgenic X1139Y hybrid maize plant is produced.

In claim 55: the recitation "an inbred parent plant" in line 7 renders the claim indefinite. It is not clear if the inbred plant in the recitation is the same as the inbred plant in the recitation "said inbred parent" in line 5. The recitation "said inbred parent" in line 5 indicates that the collection of seed comprises seed of one, not both, of the inbred parents of hybrid X1139Y.

In claim 57: the recitation "genetic identity" in line 2 renders the claim indefinite. It is not clear what is meant by this recitation: phenotypic traits, alleles, nucleotide sequences, etc. It is also not clear what is encompassed by "at least about".

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In claim 61: the recitation "produced by claim 60" renders the claim indefinite. The recitation is missing a term or phrase.

In claim 62: the claim is indefinite because it does not recite any positive method steps. The preamble indicates that the claim is directed to a method for developing a maize plant in a maize plant breeding program. However, the remainder of the claim only indicates that the plant of claim 2 is to be used as starting material. There are not steps reciting how a maize plant is developed from any breeding program.

9. Claims 42-44, 46-49, 53 and 56-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 26 December 2002 under item 7 for claims 9-19, 22-32, and 34-41. Applicant traverses the rejection in the paper received 26 March 2003. Applicant's arguments have been fully considered but were not found persuasive.

Applicant indicates that claims 9-19 and 21-43 have been cancelled, and that new claims have been added as suggested by claims faxed by Supervisory Patent Examiner Amy Nelson and Examiner David Fox (response, page 13 2nd full paragraph). However, all of the newly submitted claims were not faxed to Applicant or suggested by SPE Nelson and Examiner Fox. The claims included in this rejection do not overcome the rejection because they retain the written description issues discussed for the claims previously rejected for lack of written

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description in the previous Office actions. It is also again pointed out that "double haploid methods" is not mentioned in the specification, and is new matter, as are the methods of claims 56 and 57. The specification also does not describe all types of genes that are considered to be "value-added trait" genes. Further, the only *Bacillus thuringiensis* gene encoding a polypeptide that can confer insect resistance mentioned in the specification is Bt δ -endotoxin gene. The specification does not describe any other *B. thuringiensis* polypeptides encoding insect resistance genes, or derivatives and synthetic polypeptide modeled after any *B. thuringiensis* polypeptide.

10. Claims 46-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a method of developing a backcross conversion X1139Y hybrid maize plant, comprising backcrossing a gene into at least one of the inbred parents of X1139Y, and crossing said inbred parents to produce a transgenic X1139Y hybrid maize plant.

The specification indicates that backcrossing can be used to transfer a specific desirable trait from one inbred or source to an inbred that lacks that trait. Progeny would be homozygous for loci controlling the transferred characteristic, but will be like the superior parent for essentially all other genes (paragraph bridging pages 3-4).

However, the specification does not teach inbred plants GE565937 or GE502199 comprising only a single gene that has been introduced by backcrosses. It is not clear that single

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genes may be introgressed into the genetic background of a plant through traditional breeding. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of transferring single genes by backcross breeding taught in the prior art.

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Summary

11. Claims 1-7, 51, 52, and 54 are allowed. Claim 8 remains and claims 42-49, 53, and 55-63 are rejected. Claims 20 and 50 are objected.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular

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communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

May 28, 2003


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER